REMARKS

Claims 1-3, 11, 13-19, and 67 are pending in the present application. The Examiner rejected claim 67 under 35 USC Section 112, first and second paragraph. The Examiner rejected claims 1-5, 7, 8, 11, 13, 15, 16, 19, and 67 under 35 USC Section 102(b) as being anticipated by WO 96/22384. The Examiner rejected claims 6, 14, 17, and 18 under 35 USC 103 as being obvious over WO 96/22384 in view of Barth et al.

Claim 67 has been amended in this application. Care has been taken so that no new matter has been added.

Accompanying the Amendment under 37 C.F.R. § 1.111 dated October 2, 2003, Applicants submitted a Third Supplemental Information Disclosure Statement. Applicants respectfully request that the Examiner sign and return a copy of that Statement.

1. Claim Rejections under 35 USC Section 112

The Examiner rejected claim 67 under 35 USC Section 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. The Examiner alleges that claim 67 is confusing because it recites that cells are added "in the presence of only RPMI...". Without acquiescing to this rejection, and for purposes of clarity, the Applicants have amended claim 67 to remove the recitation of "only." Applicants respectfully assert that this rejection has been rendered moot.

The Examiner rejected claim 67 for allegedly lacking insufficient antecedent basis for "the well" in lines 12-13 of the claim. Applicants respectfully direct the Examiner's attention to line 9 of claim 67 wherein proper antecedent basis is provided by the recitation of "a well." Applicants respectfully assert that this rejection has successfully been overcome.

The Examiner rejected claim 67 under 35 USC Section 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that claim 67 contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventors, at the time of filing the application, had possession of the claimed inventions. The Examiner alleges that the application does not support a "Hodgkin's disease cell line is added to a well in presence of only RPMI with 10 % or 20% FBS. The specification at page 50 at lines 19-24 does not say Hodgkin's disease cell line is grown with 10 % or 20% FBS." Without acquiescing to this rejection, and for purposes of clarity, the Applicants have amended claim 67 to remove the recitation of "10% fetal bovine serum or." Applicants respectfully assert that this rejection has been successfully overcome.

2. Claim Rejections under 35 USC Section 102

The Examiner rejected claims 1-5, 7, 8, 11, 13, 15, 16, 19, and 67 under 35 USC Section 102(b) as allegedly being anticipated by WO 96/22384 ("Lemke"). Applicants respectfully traverse this rejection.

Lemke does not teach "[a] method for the treatment of Hodgkin's Disease in a subject comprising administering to the subject..." an antibody that "...exerts the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line..." as claimed in claim 1. A reference must be cited for what it fairly teaches. *In re Burkel*, 201 U.S.P.Q. 67 (C.C.P.A. 1979). A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. MPEP 2131. For a reference to anticipate a claim, it must *clearly and unequivocally disclose*, not merely suggest each and every element of the claimed invention as arranged in the claims. *See Idacon v. Central Forrest Products, 3 USPQ 2d 1079, 1083* (emphasis added). The Applicants respectfully assert that the Examiner has not shown where Lemke teaches an antibody that "exerts the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line" as claimed in claim 1.

Lemke teaches anti-CD30 antibodies that do not promote the release of CD30 from a cell surface, but instead inhibit the release of soluble CD30, and are specific for Hodgkin and Stemberg-Reed cells, making those antibodies

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potentially *useful in the delivery of toxins* to Hodgkin's disease cells. (*See*, page 2, ¶ 3) (emphasis added). Lemke discloses Ki-4 as an exemplary antibody. In contrast to what is claimed, Lemke does not teach an antibody that has direct cytotoxic or cytostatic activity on a Hodgkin Disease cell line without conjugation to an immunotoxin. There are no studies, examples, disclosure, or data in Lemke that show an antibody not conjugated to a toxin having any kind of anti-proliferative or killing effect on a Hodgkin Disease cell line. Additionally, there is no disclosure by Lemke in the application directed to *any* studies, data, or examples of an antibody conjugated to an immunotoxin that has a cytotoxic or cytostatic effect on a Hodgkin Disease cell line. Rather, all that Lemke can fairly teach is an antibody that does not promote the release of soluble CD30 from a cell surface and which is specific for Hodgkin and Sternberg-Reed cells. There is no disclosure as to the activity of the antibodies, either "naked" or conjugated to an immunotoxin.

The Examiner invited the Applicants to present "scientific data" to the office that "the various antibodies claimed in claim 1 of the art of record *does not have the activity recited in the instant claims* in order to obviate this rejection." (emphasis added). As discussed above, the activity recited in the instant claims includes an antibody that "exerts the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line" as recited in claim 1. Lemke discloses Ber-H2 and Ki-4 as Cluster A antibodies. Ber-H2 and Ki-4 are both "antibodies claimed in claim 1 of the art of record." Evidence shows that antibodies of Lemke's Cluster A (including Ki-4 and Ber-H2) do not have intrinsic cytotoxic or cytostatic effects; i.e., as requested by the Examiner, do not have "the activity recited in the instant claims." The Examiner is invited to review Engert *et al.*, "Evaluation of Ricin A Chain-containing Immunotoxins Directed Against the CD30 Antigen as Potential Reagents for the Treatment of Hodgkin's Disease," *Cancer Res.* 50:84-88 (1990) ("Engert"[1]). Engert *et al* discloses that Ber-H2, when not conjugated to a toxin,

[1] Cited by Applicants in the Information Disclosure Statement filed June 4, 2001 as reference AJ.

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failed to show any cytotoxicity towards Hodgkin's cell line L540 (page 86, right column, ¶ 2: "The cytotoxic effect of all of the immunotoxins was specific since the native antibodies . . . were not toxic at 10^{-6} M."). That is, Ber-H2 does not exert "the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line" as recited in claim 1. Therefore, as requested by the Examiner, Applicants have shown scientific data that "the various antibodies claimed in claim 1 of the art of record *does not have the activity recited in the instant claims* in order to obviate this rejection."

As Lemke fails to teach an antibody that "exerts the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line", Lemke cannot render claim 1, or any claim dependant therefrom, anticipated under 35 U.S.C. § 102(b).

Lemke also does not anticipate claim 8. Lemke does not teach a protein which "competes for binding to CD30 with monoclonal antibody AC10 or HeFi-1" as claimed in claim 8. Lemke, as noted above, teaches that antibodies in Cluster A are useful for the treatment of Hodgkin's disease, and that Cluster A antibodies, such as Ki-4, do not compete with Cluster C antibodies, such as HeFi-1 or AC10, for binding to CD30. Lemke teaches that Ki-4, a member of Cluster A, fails to compete with HeFi-1 in Group C. (*See* Table II, page 21). Lemke therefore fails to teach for therapeutic use antibodies that compete with HeFi-1 or AC10 for binding to CD30, and does not anticipate claim 8.

Lemke also does not anticipate claim 11. Lemke does not teach an antibody which "comprises an amino acid sequence that has at least 95% identity to SEQ ID NO:2" as claimed in claim 11. Lemke teaches antibodies in Cluster A are useful for the treatment of Hodgkin's disease. AC10 falls into Cluster C of Lemke. SEQ ID NO:2 is directed towards the amino acid heavy chain variable region of AC10. (See, page 9, Table 1). Therefore, Lemke fails to teach for therapeutic use antibodies that "comprises an amino acid sequence that has at least 95% identity to SEQ ID NO:2", and does not anticipate claim 11.

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Lemke does not anticipate claim 67. Lemke does not teach the method described in claim 67. Therefore, Lemke does not anticipate claim 67.

Because Lemke fails to anticipate claims 1, 8, 11, or 67, Lemke cannot anticipate any claims depending therefrom. Therefore, Applicants respectfully request the Examiner withdraw the rejection of these claims.

3. The Claim Rejections under 35 U.S.C. § 103

The Examiner rejected claims 6, 14, 17, and 18 under 35 USC 103 as being unpatenable over WO 96/22384 (Lemke) as applied to claims 1-5, 7, 8, 11, 13, 15, 16, and 19, and further in view of Barth et al. Applicants respectfully traverse this rejection.

Applicant submits that the subject matter of these claims is not obvious over this combination of publications because the Examiner has not provided the proper motivation for making this combination, as required by MPEP 2142-2144.

As discussed in the remarks above, Lemke fails to teach or suggest an antibody that "exerts the cytostatic or cytotoxic effect on the Hodgkin's Disease cell line...in the absence of cells other than cells of said Hodgkin's Disease cell line" as claimed in claim 1. Barth *el at* teach an immunotoxin. Barth *et al* do not teach or suggest the deficiency of Lemke.

Also, as discussed above, Lemke fails to teach or suggest an antibody that "competes for binding to CD30 with monoclonal antibody AC10 or HeFi-1" as claimed in claim 8. Barth *et al* teach a toxin conjugated to Ki-4. Lemke discloses that Ki-4 (cluster A) does not compete for binding with AC10 (Cluster C). Barth *et al* do not teach or suggest the deficiency of Lemke as recited in claim 8.

Therefore, since Barth also does not teach or suggest the deficiencies of Lemke, neither Lemke alone nor in combination with Barth can render claims 1 or 8, or any claims dependant therefrom, obvious.

CONCLUSION

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the instant application. Withdrawal of the Examiner's rejections and allowance and action for issuance are respectfully requested.

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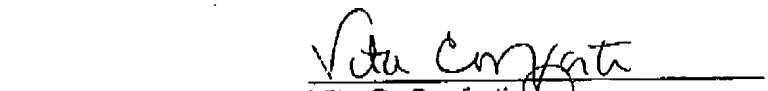
Applicant respectfully requests that the Examiner call the undersigned attorney at (425) 527-4122 if any questions or issues remain.

Respectfully submitted,



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